APR 12 2002

K020448

510(K) Summary of Effectiveness and Safety

The following summary is provided in pursuant to Section 513(I)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

A. Applicant Information

Submitter: Eastern Cranial Affiliates, 1569 20th Ave., Whitestone, New York, 11357, Phone: (516) 906-6687, Email: eca@wans.net

Contact: Joseph F. Terpenning, CO, The Terpenning Group, LLC, 2525 N. 10th St, #804, Arlington, VA 22201, Email Terpenn@wans.net , Phone 703-516-4340

- **Summary Date:** January 27, 2002

B. Device Name and Classification

- **Proprietary Name:** Static Cranioplasty Orthosis
- **Common Name:** Cranial Orthosis
- **Classification Name:** Cranial Orthosis
- **Predicate Device:** DOC™ Band, Cranial Orthosis, K964992, classified under 21 CFR § 882.5970

C. Device Description

The Static Cranioplasty Orthosis is a cranial orthosis used to treat abnormally shaped craniums in infants three to 18 months of age. This condition is clinically known as positional or Deformational Plagiocephaly. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened areas of the skull into the created spaces. The Static Cranioplasty Orthosis is only available if prescribed by a physician.

The orthosis is custom designed for each patient from a mold of the infant's head. The mold is modified and prepared for fabrication by the treating practitioner using mathematical analyses and plaster modification techniques. Each orthosis is composed of an outer shell of thermoformable plastic, an inner lining of hypoallergenic foam, a strap for securing the orthosis, and a polymer hinge and guiding system to maintain proper alignment of the orthosis. Optimum fit and alignment is insured and monitored by the same clinical practitioner.

D. Intended Use

The Static Cranioplasty Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and/or shape in infants from three to 18 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

E. Comparison to Predicate Device

The Static Cranioplasty Orthosis and the predicate device are very similar with respect to production, instructions for use, materials, safety and effectiveness, and special controls. The most significant difference between the two products is the type of thermoformable polymer used for the Static Cranioplasty Orthosis. This device utilizes Durr Plex, an optically clear polymer that allows the practitioner and the parent immediate feedback as to the condition of the child's underlying skin, thus providing an early arrest of any potential skin insults. The material is handled in an identical manner to the polymer used in the predicate device, incorporating all of the safety and standards of practice. The proposed indications of use are analogous to those presented by the predicate device, and biocompatibility, function, and effectiveness further parallel those of the predicate device.

F. Performance Data

The effectiveness of the Static Cranioplasty Orthosis has been established through clinical trials identical to those conducted using the predicate device. The effects of treatment with cranial orthoses on infants have concluded that the devices are significantly effective in correcting abnormal head shape, without evidence of relapse following treatment. Treatment with cranial orthoses is reported to improve the results of surgical correction of severe cases, often eliminating the need for further surgical intervention. Results from a pilot study conducted using the Static Cranioplasty Orthosis have determined that the device is significantly effective in realigning the asymmetrical craniums of infants, and no abnormal reactions or relapses were recorded during the study or during long term follow-ups. Statistical analyses of data collected during pre-treatment and post-treatment assessments support these findings. The Static Cranioplasty Orthosis performed almost uniformly to the predicate device during respective trials, with minor differences attributed to normal inconsistencies in data collection and deviation within normal scientifically acceptable parameters.

The safety of the cranial orthoses is established under standard biocompatibility assessments for each material used. These assessments reveal that the device and the materials used are not expected to adversely affect the infants under the intended conditions of wear. The materials are not reported to cause skin irritation or any toxic effects. Further, the product is designed to avoid improper migration or harmful levels of pressure. The interior of the device is smooth and poses no significant threat to the child during application within the normal scope of its intended use.

G. Summary

The safety and effectiveness data submitted to the FDA establishes that the Static Cranioplasty Orthosis is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Eastern Cranial Affiliates
C/O Joseph F. Terpenning, C.O.
The Terpenning Group, L.L.C.
2525 N. Tenth St., #804
Arlington, Virginia 22201

Re: K020448
Trade/Device Name: Cranial Molding Orthosis
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: January 27, 2002
Received: February 11, 2002

Dear Mr. Terpenning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020448

Device Name: Cranial Molding Orthosis

Indications For Use:

Indications for Use

The Cranial Molding Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from three to 18 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020448